UNITED STATES DISTRICT COURT DISTRICT OF NEW JERSEY

TAKEDA PHARMACEUTICAL COMPANY	
LIMITED, and TAKEDA)
PHARMACEUTICALS U.S.A., INC.)
)
Plaintiffs,) C.A. No. 20-cv-8966-SRC-CLW
v.)
NORWICH PHARMACEUTICALS, INC.,)
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ALVOGEN PB RESEARCH AND) PRETRIAL SCHEDULING ORDER
DEVELOPMENT LLC, ALVOGEN)
PHARMA US, INC., and ALVOGEN)
GROUP, INC.)
)
Defendants.)

THIS MATTER having come before the Court for a scheduling conference pursuant to Rule 16 of the Federal Rules of Civil Procedure on **November 4, 2020**, and the parties having reviewed the Court's Civil Case Management Order as well as the Local Civil Rules, and for good cause shown,

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ORDERED THAT the next event in this matter will be Plaintiff's Disclosure of Asserted Claims on November 11, 2020; and

FURTHER ORDERED that this matter will proceed as follows:

Event	L. Pat. R./Court Order	Due Date
Initial Conference	Fed. R. Civ. P. Rule 16	Wednesday, November 04, 2020
	Conference	(See ECF Nos. 25 and 29)
Plaintiffs' Disclosure of Asserted Claims	Local Patent Rule 3.6(b)	Wednesday, November 11, 2020
The parties to submit a proposed Discovery Confidentiality Order	Local Civ. Rule 5.3(b)	Tuesday, November 17, 2020

Defendants' Invalidity Contentions Due with accompanying Document Production	Local Patent Rule 3.6(c)	Friday, January 8, 2021
Defendants' Non- Infringement Contentions	Local Patent Rule 3.6(e)	Friday, January 8, 2021
Defendants' Production of Samples of API and Finished Product	Local Patent Rule 2.1	Friday, January 15, 2021
Defendants may serve interrogatories, if any, directed to date of conception and the date of reduction to practice for each asserted claim	Local Patent Rule 2.1	Tuesday, March 16, 2021
Plaintiffs' Infringement Contentions Due with accompanying Document Production	Local Patent Rule 3.6(g)	Tuesday, April 6, 2021
Plaintiffs' Responses to Invalidity Contentions Due with accompanying Document Production	Local Patent Rule 3.6(i)	Tuesday, April 6, 2021
Exchange of List of Claim Terms for Construction	Local Patent Rule 4.1	Tuesday, April 20, 2021
Exchange of preliminary proposed constructions and identification of supporting intrinsic evidence	Local Patent Rule 4.2(a)	Tuesday, May 11, 2021
Exchange of rebuttal intrinsic and extrinsic evidence	Local Patent Rule 4.2(c)	Tuesday, May 25, 2021
File Joint Claim Construction and Prehearing Statement	Local Patent Rule 4.3	Thursday, June 10, 2021
Completion of Claim Construction Discovery	Local Patent Rule R. 4.4	Monday, July 12, 2021
Opening Markman Submissions	Local Patent Rule 4.5(a)	Tuesday, July 27, 2021

Completion of Expert Claim Construction Discovery	Local Patent Rule 4.5(b)	Thursday, August 26, 2021
Responsive Markman Submissions	Local Patent Rule 4.5(c)	Monday, September 27, 2021
Propose to the Court a schedule for Claim Construction Hearing	Local Patent Rule 4.6	Tuesday, October 12, 2021
Substantial Completion of Document Production		Tuesday, November 16, 2021
Close of Fact Discovery		See Paragraph 1 below.
Deadline to amend pleadings or add parties		See Paragraphs 2 and 3 below.
Opening Dispositive and Daubert Motions		30 days after close of expert discovery
Oppositions to Dispositive and Daubert Motions		28 days after opening Dispositive and Daubert motions
Replies to Dispositive and Daubert Motions		14 days after opposition to Dispositive and Daubert motions
Pretrial Order Due		TBD
Pretrial Conference		TBD
Trial		TBD

- 1. Fact Discovery Deadline. Fact discovery is to remain open through January 28, 2022 or 45 days after the Court issues a Markman Order, whichever is later. All fact witness depositions must be completed by the close of fact discovery. No discovery is to be issued or engaged in beyond that date, except upon application and for good cause shown.
- 2. Motions to Add New Parties. Any motion to add new parties, whether by amended or third-party complaint, must be electronically filed no later than <u>January 7, 2022</u> or 45 days after the Court issues a Markman Order, whichever is later.
- **Motions to Amend Pleadings**. Any motion to amend pleadings must be electronically filed no later than <u>January 7, 2022</u>, or 45 days after the Court issues a Markman Order, whichever is later.
- **Rule 26 Disclosures**. The parties shall exchange disclosures pursuant to Rule 26 no later than November 18, 2020.

- **5. Interrogatories**. Excluding any interrogatories related to venue discovery, the parties may serve interrogatories limited to 25 single questions per side including subparts, which shall be responded to by the time provided for by the Fed. R. Civ. P and the Local Rules.
- **6. Document Requests.** The parties may serve requests for production of documents as provided by the Fed. R. Civ. P and the Local Rules.
- **7. Depositions.** Excluding any depositions related to venue discovery, the total number of fact witness depositions to be taken by each side shall be limited to 10 depositions, regardless of whether the deponent is designated as a Rule 30(b)(6) witness and/or testifying in their individual capacity; however, if a party designates multiple Rule 30(b)(6) witnesses they shall combined count as a single witness, but such Rule 30(b)(6) testimony shall not exceed 21 total hours. Each deposition is limited to 1 day of 7 hours. If a deponent requires use of a translator, the parties will meet and confer as to any hour increase required on a case-by-case basis.
- **8. Electronic Discovery**. The parties are directed to Rule 26(f), as amended, which, *inter alia*, addresses preservation of discoverable information, discovery of electronically stored information, and claims of privilege or work product protection. The parties are also directed to Local Civil Rule 26.1(d) which describes the obligations of counsel with regard to their clients' information management systems. Absent agreement of the Parties or Order of the Court, the following parameters shall apply to ESI and hard copy document productions:
 - a. General Document Image Format. Each electronic document to be produced shall be produced in single-page Tagged Image File Format ("TIFF") format with image resolution of 300 DPI or higher. TIFF files shall be single page and shall be named with a unique production number followed by the appropriate file extension. A cross-reference file (in .log or .opt format) shall be provided to indicate the location and unitization of the TIFF files. If a document is more than one page, the unitization of the document and any attachments and/or affixed notes shall be maintained as they existed in the original document.
 - **b.** Text-Searchable Documents. Document level text files shall be provided for each file to the extent that the original file has extractable text as stored in the ordinary course. No Party is obligated to generate text for a document that lacked extractable text in its native form. OCR or extracted text files shall be provided in a separate \TEXT\directory containing document level text files.
 - **c. Native Files**. A party may produce native files of a document where an image file is not a reasonable production format. Native files shall be produced in native format with associated searchable text and metadata. A party may request production of a native file of a document on a case-by-case basis.
 - **d. Metadata**. For each electronic document the following metadata should be produced and provided in a Concordance-format delimited file with a .DAT file extension, to the extent such metadata exists and is available: Page Count,

- Custodian, AllCustodian, File Path, Email Subject, Conversation Index, From, To, CC, BCC, Family Date, Date Sent, Time Sent, Date Received, Time Received, Filename, Author, Date Created, Date Modified, MD5 Hash, Native Link, File Size, File Extension, Bates Number Begin, Bates Number End, Attachment Range, Attachment Begin, and Attachment End (or the equivalent thereof).
- e. Limitations. Absent a showing of good cause, no Party need search sources that are not reasonably accessible because of undue burden or cost. Such sources, include, but are not limited to: sources intended for backup or disaster recovery purposes, such as magnetic tapes, optical disks, SANs, and other forms of backup media; legacy data from obsolete systems or systems no longer in use that is unintelligible on systems in use; deleted, slack, dynamic, or other data remaining in fragmented form, or transient data that would require forensic inspection to retrieve.
- f. Hard Copy Documents. Hard copy paper documents are to be produced as single-page TIFF images. All image files shall be produced with corresponding document level searchable text files and metadata, along with Concordance load files linking each document image with its associated searchable text and metadata. Each TIFF image shall have a unique filename associated with the corresponding Bates number. Hard copy documents should be logically unitized for production to the extent reasonably practicable. Distinct documents shall not be merged into a single record, and single documents shall not be split into multiple records. For each hard copy document, the following metadata fields shall be produced to the extent such metadata exists and is available: Custodian, Page Count, Bates Number Begin, Bates Number End, Attachment Range, Attachment Begin, and Attachment End (or the equivalent thereof).
- **9. ANDA Production.** Defendants having produced ANDA No. 214547, they shall use the same unique Bates prefix to produce any amendments or supplements thereto.
- **10. Discovery Disputes**. Please refer to the Court's Civil Case Management Order.
- 11. Motion Practice. Please refer to the Court's Civil Case Management Order.
- 12. Expert Reports. All opening expert reports from the party who has the initial burden of proof, except on the issue of objective indicia of nonobvioussness, shall be delivered by 60 days after a Markman opinion or 60 days after the close of fact discovery, whichever is later. All responsive expert reports, including any affirmative testimony regarding objective indicia of nonobviousness (including commercial success), shall be delivered by 60 days after opening expert reports. All reply expert reports from the party with the initial burden of proof shall be due 45 days after responsive expert reports. All objective indicia reply expert reports shall be due 45 days after reply expert reports. Depositions of all experts to be completed within 60 days of the objective indicia reply expert reports.
- 13. Form and Content of Expert Reports. All expert reports must comport with the form

and content requirements set forth in Rule 26(a)(2)(B). No expert shall testify at trial as to any opinions or base those opinions on facts not substantially disclosed in the expert's report and/or the parties' contentions.

- **14. Extensions and Adjournments**. Please refer to the Court's Civil Case Management Order.
- **15. Protective Orders.** Any proposed confidentiality order agreed to by the parties must strictly comply with Rule 26(c), Local Civil Rule 5.3, and applicable case law. Please also refer to the Court's Civil Case Management Order.
- **16. Local Rules.** The parties are directed to the Local Civil Rules for any other matter not addressed by this Order or the Court's Civil Case Management Order.
- **17. Status Conference.** The Court will conduct regular telephonic status conferences with counsel scheduled at the Court's convenience including:
 - March __ 2021 at __ AM/PM (Plaintiffs to initiate the call);
 - July N&021 at __ AM/PM (Defendants to initiate the call);
 - September_{NA} 2021 at __ AM/PM (Plaintiffs to initiate the call); and
 - December NA021 at AM/PM (Defendants to initiate the call).

18. FAILURE TO COMPLY WITH THE TERMS OF THIS ORDER OR ANY OTHER ORDERS WILL RESULT IN SANCTIONS.

s/Cathy L. Waldor 11/4/20

CATHY L. WALDOR United States Magistrate Judge

^{***} The Court will hold a teleconference, plainitff to intiate, 2/3/21 at 1pm.